STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor

Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

June 28, 2018 **AMENDED**

Mr. Chad Wable, CEO
Saint Mary's Hospital
56 Franklin Steet
Waterbury, CT 06706

Dear Mr. Wable:

This is an amended edition of the violation letter originally sent on June 12, 2018.

Unannounced visits were made to Saint Mary's Hospital that concluded on May 3, 2018 by a representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigation with additional information received through May 3, 2018.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by June 27, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

In accordance with Connecticut General Statutes, section 19a-496, upon a finding of noncompliance with such statutes or regulations, the Department shall issue a written notice of noncompliance to the institution. Not later than ten days after such institution receives a notice of noncompliance, the institution shall submit a plan of correction to the Department in response to the items of noncompliance identified in such notice. The plan of correction shall include:

(1) The measures that the institution intends to implement or systemic changes that the institution intends to make to prevent a recurrence of each identified issue of noncompliance;
(2) the date each such corrective measure or change by the institution is effective;
(3) the institution's plan to monitor its quality assessment and performance improvement functions to ensure that the corrective measure or systemic change is sustained; and
(4) the title of the institution's staff member that is responsible for ensuring the institution's compliance with its plan of correction.

The plan of correction shall be deemed to be the institution's representation of compliance with the identified state statutes or regulations identified in the department's notice of noncompliance. Any institution that fails to submit a plan of correction may be subject to disciplinary action.

We do not anticipate making any practitioner referrals at this time.

Connecticut Department of Public Health

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DATES OF VISIT: January 29, 30, April 5 and May 3, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

If there are any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

Complaint- CT #22173, CT#22335, CT#23123, CT#21938

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (j) Emergencies and/or (l) infection control (1).

DATES OF VISIT: January 29, 30, April 5 and May 3, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

1. Based on medical record reviews, review of facility documentation and interviews for two of three patients (Patients #7 and #9) admitted to the ED (emergency department), the facility failed to ensure that physician orders for IV (intravenous) fluid administration were followed. The finding incudes:
   a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM following a change in mental status and decreased oral intake. Nursing triage documentation at 7:02 PM indicated that the Patient's BP (blood pressure) was 98/50 (normal 120/70). Physician orders dated 5/30/18 at 7:29 PM directed an IV NS (normal saline) 1,000ml to run over 60 minutes via pump. IV documentation identified that the IV infusion was started by the nurse at 8:33 PM, was not completed within 1 hour and was completed on 5/31/18 at 12:15 AM (infusion time = 3.42 hours).
   The next set of vital signs were taken greater than 5 hours after the initial vital signs, were taken on 5/31/18 at 12:15 AM, the Patient's blood pressure had dropped to 67/54, MD #7 was notified and another IV of 1000 ml of NS was ordered to run over 60 minutes. IV documentation identified that the IV infusion was started by the nurse at 12:15 AM, was not completed within 1 hour and was completed on 5/31/18 at 2:24 AM (infusion time = 2.09 hours). The Patient's blood pressure dropped to 63/34 at 1:30 AM, 78/50 at 2:15 AM and an IV of 1000ml NS to run over 60 minutes was ordered by MD #11. IV documentation identified that the IV infusion was started by the nurse at 2:24 AM, was not completed within 1 hour and was completed on 5/31/18 at 6:19 AM (infusion time = 3.55 hours).
   Interview with Manager #1 on 5/3/18 at 10:43AM indicated that he did not know why the IV took so long to infuse as it was not documented. Interview with the ED Chief, MD #8, on 5/3/18 at 12:15 PM noted that the IVs should have been infused more timely and the nursing documentation did not indicate why the IV infused over a longer period of time.
   The facility RN job description directed to implement care regime according to standards of practice. The facility policy for standards of patient care identified that medications will be administered as prescribed.
   b. Patient #9 was admitted to the ED on 4/23/18 at 5:24 PM with flu- like symptoms. Nursing triage documentation at 5:27 PM indicated that the Patient's BP was 112/61 and temperature was 101.2 degrees Fahrenheit. Physician orders dated 4/2318 at 6:38 PM directed an IV NS 1,000ml to run over 30 minutes. Review of the IV documentation and interview with the Director of Quality on 5/3/18 at 2:10 PM identified that the IV infusion was started by the nurse at 6:45 PM, was not completed within 30 minutes as ordered and was completed on 4/23/18 at 8:46 PM (infusion time = 2 hours).
   The facility RN job description directed to implement care regime according to standards of practice. The facility policy for standards of patient care identified that medications will be administered as prescribed.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (i) General (6) and/or (j) Emergencies and/or (l)

infection control (1).

2. Based on medical record reviews, review of facility documentation and interviews for one of three patients (Patients #7) admitted to the ED (emergency department) and who had an infection, the facility failed to ensure that orders by the physician were in accordance with the facility severe sepsis protocols. and/or that potential problems were addressed by the physician. The finding incudes:
   a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM following a change in mental status and decreased oral intake. Vital sign records identified that the Patient's BP (blood pressure) was 98/50 (normal 120/70) at 7:02 PM and was 67/45 at 12:15 AM. Blood work ordered by MD #7 on 5/30/18 at 8:34 PM included, in part, a CBC (complete blood cell) count, liver function tests, and basal metabolic panel. The CBC resulted at 9:02 PM identified a high WBC (white blood cell) count of 18.8 k/uL (normal = 4.0- 10.5) and MD #7 documented that he was aware of lab results at 10:50 PM. MD #7's documentation further noted that Patient #7 would be admitted under the Hospitalist and care would be dictated by MD #10. Physician documentation dated 5/30/18 at 10:55 PM indicated that because of the high possibility of imminent life/limb threatening deterioration in condition, the hospitalist was contacted. Nursing documentation dated 5/30/18 at 1:19 AM noted MD #10 went down to evaluate the Patient, BP remains low and the ICU Resident was called to the bedside. Although the Patient's WBC count was high, and BP remained low, a lactic acid (LA) level (high level could indicate sepsis) and/or blood cultures were not ordered.
      Interview with the Sepsis Coordinator (RN #5) and/or MD #8 on 5/3/18 at 10:55 AM and 12:15 PM respectively identified that it was known at 12:15 AM on 5/31/18 that the Patient was severely septic and a LA level and pan culturing should have been ordered at this time. MD #8 further indicated that although a LA level and blood cultures were not ordered, the Sepsis treatment protocol for the ordering of IV fluids and IV antibiotics was followed and the delay in bloodwork would not have altered the Patient's treatment.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (i) General (6) and/or (j) Emergencies and/or (l) infection control (1).

3. Based on medical record reviews, review of facility documentation and interviews for one of three patients (Patients #7) admitted to the ED (emergency department) and who had an infection, the facility failed to ensure that treatment was comprehensive and/or timely. The finding includes:
   a. Patient #7 had a history of Type 2 Diabetes Mellitus and was admitted to the ED with altered mental status and decreased oral intake. Transfer documentation to the ED identified that the Patient received subcutaneous daily insulin. The initial assessment by MD #8 dated 5/30/18 beginning at 7:17 PM noted that the Patient's responses were slow and the patient did not answer most questions. Blood work ordered by MD #7 on 5/30/18 at 8:34 PM included, in part, a basal metabolic panel (BMP). The BMP resulted

at 10:49 PM identified a blood glucose level of 60mg/dl (normal = 70- 105). Although MD #7 documented that he was aware of lab results at 10:50 PM and care was turned over to MD #10, an intervention to address the Patient's low blood sugar was not ordered/performed. A finger stick blood glucose level was ordered by MD #11 (ICU Resident) at 4:11 AM, level was 55mg/dl and 2 Amps of D50 IV were administered at 4:34 per MD #11's order. The patient's blood glucose level subsequently rose to 173mg/dl at 5:09 AM on 5/31/18.
Interview with the ED Chief on 5/3/18 at 12:42 PM noted that he would have ordered the administration of ½ Amp of D50 and then check the Patient to see if there was an improvement in the patient's blood glucose level.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (e) Nursing Services (1) and/or (i) General (6) and/or (j) Emergencies.

4. Based on medical record reviews, review of facility documentation and interviews for one of three patients (Patients #7) admitted to the ED (emergency department) and who had an infection, the facility failed to ensure that a timely assessment of the Patient's vital signs was conducted. The finding incudes:
   a. Patient #7 received peritoneal dialysis for end stage renal disease and was admitted to the ED on 5/30/18 at 6:56 PM following a change in mental status and decreased oral intake. Nursing triage documentation at 7:02 PM indicated an ESI (emergency severity index) level "2" and a BP of (blood pressure) 98/50 (normal 120/70). Although the Patient's BP was not within normal range, a reassessment of the Patient's BP was not performed until 5/31/18 at 12:15 AM (5 hours later). The BP at this time was 67/54 and a second IV bolus of 1000ml of NS was ordered by MD #7 to infuse over 60 minutes.
   Interview with Manager #1 on 5/3/18 at 10:29 AM noted that the nurse should have reassessed vital signs every couple hours.
   The facility policy for emergency nursing assessment and reassessment of patients identified that those emergency patients with ESI scores of 1, 2, and 3 are reassessed with documentation of those reassessments at a minimum of every 2 hours.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (d) Medical records (3) and/or (e) Nursing Services (1) and/or (i) General (6).

5. Based on medical record reviews, review of facility documentation and interviews for one of three patients reviewed for infection (Patients #7), the facility failed to ensure that the patient's cardiac rhythm was monitored timely. The finding includes:
   a. Patient #7 was admitted to the ED (emergency department) on 5/30/18 with altered mental status and had an ESI Emergency severity index) level of 2 (1= most urgent on a

scale of 1 to 5). Vital sign records identified that the Patient's BP (blood pressure) was 98/50 (low) and respirations were 18/minute (normal) at triage on 5/30/17 at 7:02 PM. Patient #7 was then transferred to an ED room at 7:09 PM. The next assessment of vital signs was conducted on 5/31/18 at 12:15 AM (almost 5 hours later), BP was 67/54 (low) and respirations were 13/minute (low). Review of hospital documentation by Person #10 dated 7/7/17 indicated that Patient #7 was not hooked up to a heart monitor in the ED. Review of the Patient's record and interview with RN #4 on 5/3/18 at 10:43 AM noted that, patients with an ESI score of "2" would have an EKG and cardiac monitoring performed when the Patient was in the ED room and could not find documentation of this. He further identified that this would be documented in the nursing narratives and an EKG strip would be printed by the nurse and scanned into the patient's record. Review of the Patient's record and interview with RN #5 on 5/3/18 at 10:55 AM noted that the first documented EKG (electrocardiogram) was done 5/31/17 at 8:25 AM. The review and interview with RN #5 (Sepsis Coordinator) on 5/3/18 at 11:16 AM indicated that Patient #7 met the Hospital's severe sepsis criteria at 12:15 AM on 5/31/17. The facility ED sepsis order set identified, in part that nursing interventions included cardiac monitor while in the ED and a 12 lead EKG.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (c) Medical staff (3), and/or (e) Nursing service (2), (i) General (6).

6. Based on clinical record review, facility documentation and interviews for one of three sampled patients (Patient #2) who underwent a surgical procedure, the facility failed to monitor the intravenous site during a surgical procedure resulting in a significant infiltration of an extremity. The findings include:
   a. Patient #2 was admitted on 7/20/17 for a scheduled bilateral mastectomy with right sentinel node biopsy and bilateral breast reconstruction with DIEP flap procedure. The intravenous (IV) assessment sheet identified a peripheral 20 gauge IV was inserted into the left hand at 6:40AM. The IV assessment sheet identified peripheral 18 gauge IV was inserted into the left forearm at 7:55AM. Review of the intraoperative progress notes identified positioning of the patient included the left arm tucked at the patient's side with gel padding at the ulnar area and the right arm extended on an arm board with gel padding. Review of the IV assessment sheet identified that peripheral IV's were removed from the left hand and forearm in the OR at 6:00PM due to infiltration assessed 4+ edema. Review of the anesthesia record identified a total of 2500 mls Lactated Ringers was infused during the course of the procedure. Review of the operative note identified while changing the position of the patient to facilitate abdominal closure it was noted that the patient's left hand was swollen, pale and no palpable pulse. Further review identified that there had been difficulty with the IV infusion and that CRNA#1 had utilized a pressure bag to infuse the fluid because it was not running with gravity drainage. A blood pressure cuff was placed on the left upper arm. The note identified that both intravenous sites were infiltrated and that there were significant blistering along the forearm and elbow.
   Review of the orthopedic consultation progress note for date of service 7/20/17

indicated the reason for consult included IV infiltrate and concern for hand and forearm compartment syndrome. The progress note identified upon exam of the left upper extremity a palpable radial pulse was present and compartment pressure measurements were performed. Further review identified that compartment syndrome was not a concern, compartment release was not required, however, a recommendation of close observation of the left upper extremity, strict elevation and splinting. Review of the physician progress note dated 7/21/17 identified left upper extremity less swollen, good movement and blisters intact. The physician progress note dated 7/22/17 identified patient denies any complete paresthesia of left upper extremity, neurovascular intact and able to actively flex and extend all digits and wrist with no pain.

Review of the discharge note dated 7/23/17 identified left arm with unroofed blisters, improved sensation to digit four and five, good capillary refill and range of motion and to continue with elevation of left upper extremity and daily wound care. Review of the facility investigation and documentation identified during this type of procedure no pressure bags with peripheral IV infusions and an alternative IV access should be considered i.e. central line, midline or PICC placement and the use of alternative devices for hemodynamic monitoring.

Interview on 1/30/18 at 10:50AM with the Chief of Anesthesia (MD#1) identified he was not involved with Patient#1's surgery however, he identified positioning of a patient is a team effort and if an arm is tucked in anesthesia must ensure that the IV infusion is monitored. MD#1 further identified monitoring of the IV site should be done at a minimum once every hour or more if necessary, this would include anesthesia personnel checking under the sterile drapes to evaluate the extremity and if visualization is required communication with surgical team should be done.

Interview on 1/30/18 at 2:00PM with the CRNA#1 identified she was assigned to Patient#2 and recalls there was a peripheral IV in the left forearm and that she inserted a second peripheral IV in the left arm. CRNA#1 identified a blood pressure cuff was placed above the IV sites on the left forearm and prior to surgical draping the IV infusions were running appropriately. CRNA#1 further identified prior to noon she noted the IV infusion was slowing; she informed the surgical team to be aware of their proximity to the patient's left side in addition to checking the IV tubing position. CRNA#1 did not visualize the arm, felt no obvious edema and the IV infusion appeared to be flowing. CRNA#1 stated about an hour later the IV infusion was slow and utilized a pressure bag to increase the flow. CRNA#1 identified at approximately 4:30PM the surgical team requested the O.R table to be flexed to reposition the patient and at this time she was able to visualize the left arm. CRNA#1 indicated the left arm had blisters, was edematous below the blood pressure cuff, no palpable radial pulse and fingers were purple. CRNA#1 identified the IV infusions were stopped, removed the blood pressure cuff while the surgical team assessed the arm. CRNA#1 identified positioning of the arm was done by the surgical team and that she was aware of the arm position.

Interview on 1/31/18 at 10:25AM with the orthopedic physician (MD#2) identified he evaluated the patient's left arm while he/she was in the operating room. MD#2 identified the initial concern of compartment syndrome developing was not warranted because the compartment pressure measurements were within normal limits. MD#2 further

identified blistering is very common with an IV infiltration and that the plan of care for Patient#2 included monitoring and elevation of the extremity.
Review of the facility's patient positioning policy identified in part a preoperative assessment for positioning prior to surgery and that assessment includes type and length of procedure. The anesthesia provider monitors and maintains the physiological functioning of the patient and his/her requirements for anesthesia. Review of the short peripheral IV catheter insertion and maintenance policy identified in part frequency of peripheral IV site assessments for continuous IV drip to assess every two hours.

The following is a violation of the Regulations of Connecticut State Agencies Section 19-13-D3 (e) Nursing service, and/or (i) General, and/or (l) Infection control.

7. Based on clinical record review, facility documentation and interviews for one of three sampled patients (Patient #1) who were at risk for skin breakdown, the facility failed to ensure that care and services were provided to prevent a pressure ulcer developing. The findings include:
   a. Patient #1 was admitted on 8/22/17 status post fall at home with a diagnosis of right femur fracture. Patient #1's diagnoses include end stage renal disease (ESRD) on dialysis, chronic obstructive pulmonary disease (COPD) and atrial fibrillation. Review of the clinical record on 8/22/17 at 9:57PM, identified that documentation of a head to toe nursing admission assessment was performed and the Braden scale risk assessment calculated a score of 17 (high risk). Review of the plan of care dated 8/22/17 at 11:39PM identified a problem of skin integrity with a goal to promote tissue integrity and outcome as progressing. Review of the brief operative note dated 8/24/17 identified that Patient #1 underwent open reduction internal fixation of right femur fracture. Review of the flowsheet shift assessment dated 8/24/17 at 11:00AM identified prophylactic foam dressing applied to the sacrum and a Braden scale risk assessment score of 11. Review of the flowsheet shift assessment on 8/25/17 at 3:45AM identified skin color ecchymosis, prophylactic foam dressing applied and a Braden scale risk assessment score of 14. The neurosurgical consult note dated 8/26/17 identified on 8/25/17, Patient#1 complained of inability to move his/her legs and decreased sensation. The assessment identified sudden onset of acute lower extremity paralysis. Review of the flowsheet shift assessment on 8/27/17 identified that the sacrum area was first assessed at 10:19pm and indicated that the patient had a pressure injury, large ecchymosis with small open areas. Further review identified that the wound was present on hospital admission and not hospital acquired. The assessment further described the pressure ulcer stage as deep tissue injury (DTI), state of healing ecchymotic, wound bed maroon/purple, peri-wound skin clean dry intact, round shape measuring 7cm x 6cm with scant sanguineous drainage. Further review identified that the dressing was changed and replaced with a foam (Allevyn) dressing. The flowsheet shift assessment dated 8/28/17 at 1:00AM identified DTI(deep tissue injury) pressure ulcer, dressing clean, dry and intact; at 6:32AM identified DTI pressure ulcer, dressing changed, wound bed maroon/purple, no drainage, barrier cream applied and repositioned onto left side. Review of the wound care consult note dated 8/28/17 at 5:20PM

identified DTI of the sacrum measuring 7cm x 12cm, no drainage, ecchymosis present and erythema. Review of the wound care orders directed to apply Allevyn sacral dressing, change every other day and a pressure redistributing low air loss mattress. Further review identified to follow up on discharge to evaluate how the wound progresses since the extent of the injury is unknown. Review of the flowsheet assessment dated 8/29/17 at 5:00PM identified dressing status clean, dry and intact. The flowsheet assessment dated 8/30/17 at 12:00PM identified patient repositioned every two hours and on 8/31/17 dressing assessed and changed. Review of the plan of care note dated 8/31/17 at 8:05AM identified that Patient #1 was on a Clinitron (air fluidized mattress) bed. Review of the clinical record from 8/22/17 thru 8/31/17 failed to reflect consistent documentation of patient repositioning every two hours or other interventions used for pressure ulcer prevention. Review of the wound care consult note dated 8/31/17 at 2:30PM identified sacrum with large DTI, unchanged and potential for area to turn into an unstageable ulcer which will need debridement. Review of the discharge summary dated 8/31/17 identified Patient #1 continued to have bilateral lower extremity flaccid paralysis and numbness, the patient was transferred to another facility for higher level of care on 8/31/17.

Interview on 1/29/18 at 2:00PM with the Unit Nurse Manager (RN#3) failed to provide documentation that the patient was turned and/or repositioned every two hours. RN#3 indicated that all mattresses at the facility are deemed air pressure relieving and that staff do not document when a patient is repositioned every two hours because it is standard of care. RN#3 further identified that during change of shift nursing staff will communicate when the patient requires repositioning.

Review of the facility's procedure documentation for pressure injury prevention identifies in part that a DTI results from prolonged pressure, treatment includes methods to decrease pressure and to turn and reposition the patient every 1 to 2 hours or more frequently as required.